K101519

510(k) Summary of Safety and Effectiveness

NOV - 5 2010

SUBMITTER:	Sofradim Production 116, avenue du formans 01600 Trevoux, France Phone: 33 0 4 74 08 90 00
CONTACT PERSON:	James McMahon Manager, Regulatory Affairs Covidien 15 Crosby drive Bedford, MA 01730 USA Phone: (781) 839 1787
DATE PREPARED:	May 28, 2010
TRADE/PROPRIETARY NAME:	PARIETEX™ Plug and Patch
COMMON/USUAL NAME:	Surgical Mesh
CLASSIFICATION NAME:	Mesh, Surgical, Polymeric
PREDICATE DEVICE(S):	BARD® MESH PERFIX® PLUG (K922916) PARIETEX PROGRIP™ Mesh (K081050) PARIETEX™ Lightweight Monofilament Polyester Mesh (K090858) PARIETEX™ PARASTOMAL MESH (K081126)
DEVICE DESCRIPTION:	PARIETEX™ Plug and Patch is a kit composed of: • A pre-cut non absorbable patch made out of polyester monofilament. • A semi-absorbable disk made from the assembly of two textile layers. This disk is composed of polyester monofilament and polylactic acid monofilament.
INTENDED USE:	PARIETEX™ Plug and Patch is indicated for the reinforcement of soft tissues during repair of groin hernia defects by open approach.
TECHNOLOGICAL CHARACTERISTICS:	The technological characteristics of PARIETEX™ Plug and Patch are similar to those of the predicate devices. The patch and the disk of the PARIETEX™ Plug and Patch are manufactured with knitted monofilament polyester and monofilament polylactic acid threads.
MATERIALS:	PARIETEX™ Plug and Patch is comprised of biocompatible materials that are in compliance with ISO 10993-1 and/or USP standards.
PERFORMANCE DATA:	Bench testing has been conducted to evaluate the performance characteristics of PARIETEX™ Plug and Patch. Testing has shown that the PARIETEX™ Plug and Patch is equivalent in performance characteristics to the predicates PARIETEX™ Lightweight Monofilament Polyester Mesh, PARIETEX PROGRIP™ Mesh and BARD® Mesh PerFix® Plug.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Sofradim Production
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Mr. James McMahon
Manager, Regulatory Affairs
15 Crosby Drive
Bedford, Massachusetts 01730

NOV - 5 2010

Re: K101519
Trade/Device Name: PARIETEX™ Plug and Patch
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: October 29, 2010
Received: November 02, 2010

Dear Mr. McMahon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101519

Indications For Use

NOV - 5 2010

510(k) Number (if known): K101519

Device Name: PARIETEX™ Plug and Patch

Indications For Use:

PARIETEX™ Plug and Patch is indicated for the reinforcement of soft tissues during repair of groin hernia defects by open approach.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101519